I. Preliminary Remarks and Amendments

Claims 1, 4-5, 8, 10, 53-55, 68-69, and 75-76 are currently pending and are under examination. Claims 1, 55, and 68 are amended herein, and claims 2-3 and 11 are canceled herein. Support for the amendments to the claims is found throughout the specification, including page 13, lines 16-21; page 14, lines 11-13; page 28, line 3 through page 29, line 2; page 86, lines 11-18; page 89, line 14, through page 91, line 4; pages 93-96; and Figure 2. Accordingly, the amendments do not include new matter. The Applicants do not intend with these or any other amendments to abandon the subject matter of claims previously presented, and reserve the right to pursue such subject matter in duly filed patent applications.

II. Patentability Arguments

A. The Rejections Under 35 U.S.C. § 102(a) May Properly Be Withdrawn.

1. Virca does not anticipate the subject matter of any pending claim

The Examiner rejected claims 1-8, 10-11, 53-55, 68-69, and 75 under 35 U.S.C. § 102(a) in view of either of two references, as set out below. The applicants initially note that claims 6 and 7 were previously canceled and the outstanding rejection insofar as it applies to pending claims 1-5, 8, 10-11, 53-55, 68-69, and 75. These pending claims were rejected under 35 U.S.C. § 102(a) as being anticipated by Virca et al. (U.S. Patent No. 6,387,676; hereafter "Virca"). *See* Office Action at page 9. In support, the Examiner asserted that Virca taught a DNA sequence (Virca's SEQ ID NO: 3) that matched residues 300-1006 of SEQ ID NO: 1 of the instant application. Thus, Virca's polynucleotide assertedly anticipates claims 1-2 and 11, because it can hybridize to SEQ ID NO: 1 under moderately or highly stringent conditions. Virca's polynucleotide also assertedly anticipates claim 3 because it comprises at least 16 nucleotides of SEQ ID NO: 1. Virca was further characterized as disclosing vectors and host cells that assertedly anticipate claims 4-7 and 55, and as disclosing methods of recombinantly expressing DNA that assertedly anticipate claims 8 and 10. In response, the Applicants submit that Virca does not disclose each limitation of any one of the rejected claims, as amended.

Virca does not disclose the sequence set forth in SEQ ID NO:1 of the instant application. Virca also does not disclose a nucleotide sequence that encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:2 of the application. For example, the nucleotide sequence disclosed by Virca does not encode the C-terminal 40 amino acids of SEQ

ID NO:2, the amino acids encoded by nucleotides 1003-1122 of SEQ ID NO:1. Consistently, Virca's polypeptide comprises an amino acid sequence (SEQ ID NO:9 in Virca) that lacks those same 40 amino acids at the C-terminus of SEQ ID NO:2 of the instant application. Accordingly, Virca does not disclose, expressly or inherently, any of the following: (1) a polynucleotide comprising SEQ ID NO:1, (2) a polynucleotide comprising nucleotides 49-1122 of SEQ ID NO:1, (3) a polynucleotide encoding a polypeptide comprising the sequence of SEQ ID NO:2, or (4) polynucleotides comprising sequences complementary to any of (1)-(3). Thus, Virca does not disclose each element of any of independent claims 1 or 68.

As a matter of law, a dependent claim incorporates each limitation of a claim from which it depends. 35 U.S.C. § 112, fourth paragraph. Claims 4, 5, 8, 10, 53, 54, 55, and 75 each ultimately depend from claim 1. Claim 69 depends directly from claim 68. Each of the rejected dependent claims thus ultimately depends from one of independent claims 1 or 68 and, as established above, Virca does not disclose each element of any of those independent claims, as amended. Accordingly, Virca cannot disclose, expressly or inherently, each element of any of dependent claims 4-5, 8, 10, 53-55, 69 or 75 and, for that reason, Virca does not anticipate the subject matter of any of those dependent claims.

For the foregoing reasons, Virca does not anticipate the subject matter of any of claims 1, 4-5, 8, 10, 53-55, 68-69 or 75 under 35 U.S.C. § 102(a) and, therefore, the rejection should be withdrawn.

2. Tang is not available under 35 U.S.C. § 102(a) against the pending claims

On page 10 of the Office Action, the Examiner rejected claims 1-5, 8, 10-11, 53-55, 68-69, and 75-76 under 35 under 35 U.S.C. § 102(a) as being anticipated by Tang et al. (U.S. 2002/0197679, 12/26/2002; hereafter "Tang"). In support, the Examiner asserted that Tang discloses a DNA sequence (SEQ ID NO:271) encoding a kinase that displays 97% overall homology to SEQ ID NO: 1 of the instant application. Thus, Tang assertedly anticipates claims 1-2 and 11, because it discloses a polynucleotide that can hybridize to SEQ ID NO: 1 under moderately or highly stringent conditions. Tang's sequence also assertedly anticipates claim 3 because it comprises at least 16 nucleotides of SEQ ID NO: 1. Tang was further characterized as disclosing pharmaceutical compositions, diagnostic and therapeutic agents, and arrays, which assertedly anticipate claims 53-54 and 75-76 of the instant application.

To invalidate a claim under 35 U.S.C. § 102(a), the invention must be known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent. On its face, Tang bears a publication date of December 26, 2002. The instant application was filed on July 19, 2001 and claims a priority benefit extending back to July 19, 2000. Thus, the effective filing date of the application is July 19, 2000. The filing of a U.S. patent application is recognized as a constructive reduction to practice of the claimed invention. Because Tang was not published prior to the effective filing date of the instant application, or even before the actual filing date of the present application, the Tang reference was not published prior to the Applicants' invention. Accordingly, Tang is not properly available as art against the pending claims under 35 U.S.C. § 102(a) as a matter of law. Accordingly, the rejection of claims 1-5, 8, 10-11, 53-55, 68-69 and 75-76 under 35 U.S.C. § 102(a) over Tang is improper and should be withdrawn.

B. The Rejections of Claims 1-5, 8, 10-11, and 61-63 under 35 U.S.C. § 112, First Paragraph, May Properly Be Withdrawn.

1. Written Description

The Examiner rejected claims 2-3, 11, and 68-69 under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement for 1) a genus of DNA sequences encoding a polypeptide that exhibits 70% identity to SEQ ID NO: 2, where said polypeptide has the same activity as SEQ ID NO: 2 (e.g., kinase activity); 2) a genus of DNA fragments of SEQ ID NO: 1, (a) or (b), encoding a polypeptide of at least 25 amino acid residues wherein the polypeptide retains kinase activity; 3) a genus of DNA sequences encoding a polypeptide that has substitutions and/or deletions of 1-358 amino acid residues of SEQ ID NO: 2, wherein said polypeptide retains an activity (e.g., kinase activity); 4) a genus of reagents comprising a DNA sequence encoding fragments, allelic variants, splice variants, and homologs of SEQ ID NO: 2 with no specifically recited activity; 5) a genus of DNA fragments of SEQ ID NO: 1, comprising at least 16 bases, wherein the DNA sequence does not encode a product with an activity (e.g., kinase activity); and 6) a genus of DNA sequences complementary to the above products. The Applicants respectfully traverse this rejection and submit that the claims, as originally filed and as amended, are adequately described in the specification.

To expedite prosecution, the Applicants have amended claims 1 and 68 to remove references to "hybridization," fragments, and variants, and have canceled claims 2-3 and 11. The claimed polynucleotides are defined by structural limitations such as the complete primary

sequence of a polynucleotide comprising a h2520-59 coding sequence or a complement thereof. This lever of structural definition is sufficient to define the subject matter being claimed in a manner that allows one of skill in the art to conclude that the inventors possessed what is claimed as of the effective filing date. Accordingly, the claims as amended satisfy the requirement for written descriptive support mandated by 35 U.S.C. § 112, first paragraph.

Consequently, the rejection of claims 2, 3, 11, 68, and 69 under 35 U.S.C. § 112, first paragraph, for asserted lack of written description, has been rendered moot by amendment. Accordingly, the rejection should be withdrawn.

2. Enablement

Claims 2-3, 11, and 68-69 were also rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement for assertedly not teaching how to make and use 1) DNA sequences encoding a polypeptide that exhibits 70% identity to SEQ ID NO: 2, where the polypeptide has the same activity as SEQ ID NO: 2 (e.g., kinase activity); 2) DNA fragments of SEQ ID NO: 1 encoding a polypeptide of at least 25 amino acid residues wherein the polypeptide retains an activity (e.g., kinase activity); 3) a DNA sequence encoding a polypeptide that has substitutions and/or deletions of 1-358 amino acid residues of SEQ ID NO: 2, wherein the polypeptide retains an activity (e.g., kinase activity); 4) reagents comprising a DNA sequence encoding fragments, allelic variants, splice variants, and homologs of SEQ ID NO: 2 with no specific activity; 5) DNA fragments of SEQ ID NO: 1, comprising at least 16 bases, wherein the DNA sequence does not encode a product with an activity (e.g., kinase activity); and 6) DNA sequences complementary to the above products. The Applicants respectfully traverse this rejection and submit that the full scope of each of the pending claims, as originally filed and as amended, are enabled.

To expedite prosecution, the Applicants have amended claims 1 and 68 to remove references to "hybridization," fragments, and variants, and have canceled claims 2-3 and 11. The claimed polynucleotides satisfy the enablement requirement by providing sufficient disclosure to teach one of skill in the art how to make and use the claimed invention without requiring undue experimentation. In the instant case, the quantity of required experimentation is minimal and is routine because the Applicants have taught the reference polynucleotide sequence in SEQ ID NO: 1 and the reference amino acid sequence in SEQ ID NO: 2. This guidance, coupled with the

knowledge in the art, provides sufficient direction to allow one of skill to construct, test and identify (i.e., make), as well as use, the claimed molecules.

For the foregoing reasons, the rejection of claims 2, 3, 11, 68 and 69 under 35 U.S.C. § 112, first paragraph, for asserted lack of enablement, has been rendered moot by amendment. Accordingly, the rejection should be withdrawn.

C. The Rejection of Claims 1-5, 8, 10-11, 53-55, 68-69 and 75-76 under 35 U.S.C. § 112, Second Paragraph, May Properly Be Withdrawn.

The Examiner rejected claims 1-5, 8, 10-11, 53-55, and 75-76 under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to clearly identify the "activity" of the polypeptide comprising the amino acid sequence of SEQ ID NO: 2 in claims 1-3. Claims 1-2, 4-5, 8, 10-11, 53-55, and 75-76 were rejected for reciting the term "moderately or highly stringent conditions." Claims 68-69 were rejected as assertedly indefinite because the phrase "variant" in claim 68, and its dependent claim 69, is unclear. The Applicants respectfully traverse this rejection and submit that the claims, as originally filed and as amended, clearly and definitely define the subject matter of the claims in compliance with 35 U.S.C. § 112, second paragraph

To expedite prosecution, the Applicants have amended claim 1 to remove the hybridization language, have amended claim 68 to remove fragments and variants, and have canceled claims 2-3 and 11. Moreover, the claims as amended no longer require a definition for h2520-59 "activity." However, the Applicants disagree with the Examiner's contention that "an activity" of h2520-59, as defined in the specification, is referring to kinase activity only. h2520-59 activity, as discussed throughout the specification, including at page 86, lines 11-18, Example 2 (pages 89-91), and Example 7 (pages 95-96), may encompass a variety of activities and should not be interpreted as being limited to kinase activity only. The specification provides evidence that h2520-59 expression is clearly elevated in cancer cells, providing a useful diagnostic/prognostic activity in detecting a variety of human cancers. Moreover, the elevated expression of h2520-59 in cancer cells has been confirmed in a post-filing publication by Bowers et al., *Oncogene* 22:2823-2835, 2003 (attached as Appendix A). Accordingly, the Applicants respectfully disagree with the Examiner's assertion that h2520-59 activity is limited to kinase activity.

For all of the foregoing reasons, the Applicants submit that the rejection of claims 1-5, 8, 10-11, 53-55, 68-69, and 75-76 under 35 U.S.C. § 112, second paragraph, for indefiniteness, has been rendered moot by amendment and, for that reason, the rejection should be withdrawn.

CONCLUSION

The Applicants submit that pending claims 1, 4-5, 8, 10, 53-55, 68-69, and 75-76, as amended, are now in condition for allowance. Expedited notification thereof is respectfully requested.

Respectfully submitted,
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